

K072037

**510(k) Premarket Notification**

for

**AUG - 8 2007**

**Life-Shield Products, Inc.**

**CAREO Safety Syringe for U-100 Insulin 0.5cc/mL**

*(per 21 CFR807.92)*

**1. Sponsor**

Life-Shield Products, Inc.

3Fl., No. 10, Wuchiuan 7<sup>th</sup> Rd.,

Wugu Industrial Park,

Taipei 248

Taiwan, R.O.C.

Contact Person: Mr. Hsiao, Chung-Chih

Telephone: +886 2 2299 6033

Fax: +886 2 2299 6035

Date Prepared: July 15, 2007

**2. Device Name**

Proprietary Name: CAREO Safety Syringe for U-100 Insulin 0.5cc/mL

Common/Usual Name: Syringe

Classification Code: MEG

Classification Name: Syringe, Antistick

**3. Predicate Device**

- InsoSAFE<sup>TM</sup> Bak'SNAP<sup>TM</sup> Retractable Insulin Safety Syringe (K050131)
- CAREO Safety Syringe for U-100 Insulin (K061055)

**4. Device Description**

The Life-Shield Products, Inc., CAREO Safety Syringe for U-100 Insulin 0.5cc/mL is a sterile, single use and disposable, 0.5cc/mL piston syringe, provided with a permanently attached needle in nine product configurations. The CAREO Safety Syringe for U-100 Insulin 0.5cc/mL is similar in appearance, size, materials operation, and purpose to the cited predicate device and other conventional single use, sterile, disposable syringes.

Appendix K- page 1

**5. Intended Use**

The CAREO Safety Syringe for U-100 Insulin 0.5cc/mL is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for injection of insulin into a patient.

The CAREO Safety Syringe for U-100 Insulin 0.5cc/mL is also intended to prevent needlestick injuries. In addition, when the user breaks the plunger, reuse of the syringe is prevented.

**6. Technological Characteristics and Substantial Equivalence**

Life-Shield Products, Inc., makes a claim of substantial equivalence of the CAREO Safety Syringe for U-100 Insulin 0.5cc/mL to the InsoSAFE™ Bak'SNAP™ Retractable Insulin Safety Syringe (K050131) and CAREO Safety Syringe for U-100 Insulin (K061055) based on similarities in intended use, design, technological and operational characteristics. All are indicated for injecting fluids (insulin) into the body, while helping to reduce the risk of sharps injuries. All syringes are piston syringes that use permanently attached single lumen hypodermic needles. All syringes are provided sterile, single-use, and disposable. All syringes require the user to manually retract the needle-plunger into the syringe barrel, snap off the plunger rod, and discard the pieces.

**7. Summary for testing of material and simulated use study**

The materials of construction, safety feature, and other functional and performance characteristics of CAREO Safety Syringe for U-100 Insulin 0.5cc/mL are identical to those for the other CAREO Safety Syringes. The material safety test, biocompatibility, and safety feature were already indicated, verified, and validated as shown in the previous 510(k) premarket notifications [K030976, K052397, K060208, and K061055]. Therefore, no new tests are necessary.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 8 2007

Life-Shield Products, Incorporated  
C/O Ms. Rosina Robinson  
Senior Staff Consultant  
Medical Device Consultants, Incorporated  
49 Plain Street  
North Attleboro, Massachusetts 02760

Re: K072037

Trade/Device Name: CAREO Safety Syringe for U-100 Insulin 0.5cc/mL  
Regulation Number: 880.5860  
Regulation Name: Piston Syringe  
Regulatory Class: II  
Product Code: MEG, FMF  
Dated: July 24, 2007  
Received: July 25, 2007

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K072037

Device Name:

Life-Shield Products, Inc., CAREO Safety Syringe for  
U-1 00 Insulin 0.5cc/ML

Indications For Use:

The CAREO Safety Syringe for U-100 Insulin 0.5cc/mL is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for injection of insulin into a patient.

The CAREO Safety Syringe for U-100 Insulin 0.5cc/mL is also intended to prevent needlestick injuries. In addition, when the user breaks the plunger, reuse of the syringe is prevented.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   x   \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K072037